

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460 OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DOCUMENT CONTAINS CONFIDENTIAL BUSINESS INFORMATION

DP BARCODE No.: <u>D459316</u>; FILE SYMBOL/REG. No.: <u>35935-48(altCSF#1)</u>; PRODUCT NAME: <u>Lambda-Cyhalothrin Technical</u>; DECISION No.: <u>565237</u>; PC Code(s): <u>128897</u>; ACTION CODE: <u>R351</u>; FOOD Use: <u>Yes</u>; REGISTRANT: <u>NuFarm Limited</u>; e-Submission #<u>54244</u>; <u>Submission #:</u> <u>1056527</u>

DATE: April 29, 2021

SUBJECT: Summary of Product Chemistry Review of "Lambda-Cyhalothrin Technical"

FROM: Shyam Mathur,

Product Chemistry Team Leader

CITAB / RD (7505P)

THROUGH: Kerry Leifer, Branch Chief,

CITAB/RD (7505P)

TO: Robert Mitchell / Jacquelyn Herrick, PM 04,

I-V Branch 1 / RD (7505P)

Active Ingredient(s): Lambda-Cyhalothrin (97.34%); Product label Claim: 95.0%

MRID No(s).: 51192701: (Group A Data – 830.1600 to 830.1670, 830.1700 and 830.1800)

51192702: (Summary group B data – physical-chemical properties)

Deficiencies: Yes

CONCLUSION:

Group A: Acceptable: All required data submitted to support the proposed Alternate CSF#1.

Group B. Acceptable, except for the guideline 830.7050 (UV-VIS) and 830.6314 (compatibility/non-compatibility). The registrant must submit or cite the results of these two studies.

CSF:

Proposed Alt CSF #1:(97.34%, dated: July 6, 2020) - Acceptable

(5-batch analysis results on Page #12 of this report)

(Production site- NuFarm Limited, 4020 Aerial Centre Parkway, Suite 101, Morrisville, NC 27560, USA

Contact Person: Carrie Tackema- Telephone No.: 919-379-2528)

<u>Current Basic CSF:</u> (95.0%, dated: October 8, 2008) – Accepted on 10-15-2008 (PCR dated 10-15-2008, DP354105 & 357216))

(<u>Production site</u>- Youth Chemical Company Limited, 3 Dalian Road, Yangzhou Chemical Industry Zone, Yizheng, Jiangsu, China)

Alternate CSF(s) in compliance with 40CFR§152.43: Yes [X]; No []; NA [X]

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Similarity to cited product

[]Similar

[] Not similar

[] Identical

[x] Not applicable

[] Not Determined – Since the accepted basic CSF for the cited product was not available, similarity decision could not be made

Product label: Recommendations: Yes []; No []; NA X]

830.1550 (product identity & composition) [MRID No. 51192701]

Common name/alias: Lambda-Cyhalothrin

Systematic Name: Cyclopropanecarboxylic acid, 3-[(1Z)-2-chloro-3,3,3-trifluoro-1-

propenyl]-2,2-dimethyl-, (R)-cyano(3-phenoxyphenyl)methyl

ester, (1S,3S)-rel-

Molecular formula: C23H19CIF3NO3

Molecular weight: 449.86

CAS No.: 91465-08-6

Structure:

Manufacturing facility:

NuFarm Limited, 4020 Aerial Centre Parkway,

Suite 101, Morrisville, NC 27560, USA

Contact Person: Carrie Tackema- Telephone No.: 919-379-2528)

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830.1800. Enforcement analytical method [MRID No. 51192701]

Summary

Identification and quantitative determination of the lambda-cyhalothrin active ingredient content of the test item was performed using GC-MS as compared to a lambda-cyhalothrin analytical reference material (external standard), ref JRF Study Number: 227-2-12-0971. Validation of the analytical methodology is described in ref JRF Study Number: 227-2-12-0971, Appendix 3.

Note: Additional GLP reports submitted with the 5-batch analysis describe validated GC-FID and HPLC-UV methodologies for quantitation of lambda-cyhalothrin, ref JRF Study Numbers 232-2-12-0972 and 10200, respectively

Apparatus & experimental parameters

GC-MS System: Agilent 7890/5975C

Instrument: GC-MS

HP-5 MS; 30 m x 0.25 mm (i.d.) x 0.25 µm film thickness Column:

Carrier:

Flow: 1 mL/min

Injector:

240°C

Column oven: 80°C (hold for 2.0 minutes)

80 - 265°C (25°C/minute)

265°C (hold for 8.0 minutes)

Transfer line:

Analyte retention time: lambda-cyhalothrin ~12.65 minutes

Run time: ~17.5 minutes

Detector: EI SCAN 40-500 m/z

Details of the analytical method can be seen under the MRID No. provided above. Analytical method was validated.

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GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	51192702	Α	White@ 31°C
830.6303	Physical state	51192702	Α	Solid Powder@ 31°C
830.6304	Odor	51192702	Α	Aromatic odor@ 31°C
830.6313 830.6317	Stability to normal and elevated temperatures, metals, and metal ions		G	No data submitted
830.6314	Oxidation/reduction: chemical incompatibility	51192702	U	Test was conducted with barium nitrate + powdered cellulose, which clearly indicated that it has no oxidizing properties. But the compatibility/non-compatibility test was not performed with commonly used chemicals.
830.6315	Flammability	51192702	Α	Considered not flammable
830.6316	Explodability	51192702	Α	Not explosive
830.6317	storage stability	51192702	A	TS was found to be stable 8 weeks (56 days)* at 40°C when stored in PE/EV containers with respect to active ingredient contents. The active ingredient determination was performed with validated GC-FID method with external standard cal bration. The analytical method was validated for linearity, precision and accuracy.
830.6319	Misc bility	51192702	NA	The active ingredient is not an emulsifiable liquid and will not be diluted with petroleum solvent.
830.6320	Corrosion characteristics	51192702	А	No corrosion to packaging PE/EV after putting into contact for 56 days at 40±2 °C. No apparent reaction was observed with respect to weight loss and reaction. Packaging material was found be compatible with TS during the study period.
830.7000	pH	51192702	Α	5.95 (1% w/v in water; @20 °C).
830.7050	UV/Visible absorption	51192702	U	Technical is a solid powder
830.7100	Viscosity	51192702	NA	TS is a solid
830.7200	Melting point	51192702	А	47.3°C.
830.7220	Boiling point	51192702	NA	TS is a solid
830.7300	Density	51192702	Α	0.9267 g/ml (7.81 bs/gal) .@ 20 °C
830.7370	Dissociation constants in water (DC)	51192702	Α	TS did not dissociate in water
830.7550	Partition coefficient	51192702	Α	Log Po/w = 6.61 @ 20°C
830.7840	Solubility (water)	51192702	А	See solubility in water & organic solvent @20 C under organic solvent
830.7950	Vapor pressure	51192702	А	7.48 x 10 ⁻⁷ Pa @ 20°C

A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress;

U = Up-grade (additional information required); W = waivers

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*830.6317 (ss): these conditions were chosen since the m. p. of the test substance was 49.2°C

Note 1 (solubility)830.7840[MRID No. 51194702]

Overall mean solubility of Lambda-cyhalothrin Technical in buffer water (pH 5.04) = 0.0000063 ± 0.0000003 g/L@20 $\pm1^{\circ}$ C (pH 7.03) = 0.0000058 ± 0.0000004 g/L@20 $\pm1^{\circ}$ C (pH 9.04) = 0.0000063 ± 0.0000002 g/L@20 $\pm1^{\circ}$ C The solubility of Lambda-cyhalothrin Technical (g/L)@20 $\pm1^{\circ}$ C in Acetone >250; 1,2-Dichloroethane >250; Ethyl Acetate >250; n-Heptane 67-80; Methanol >250; p-Xylene >250

